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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
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10/720,213

11/25/2003

Nyle Elliott

A-8730

4978

20741

7590

12/29/2010

Welsh Flaxman & Gitler

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Alexandria, VA 22314

EXAMINER

MENDEZ, MANUEL A

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

12/29/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/720,213 | Applicant(s) ELLIOTT ET AL. | |
| | Examiner Manuel A. Mendez | Art Unit 3763 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 October 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 7-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 7-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4 and 7-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Kelly** (US 4,547,187) in view of **Fisher** et al. (US 4813422; hereafter Fisher), **Thornton** (US 6,811,559), **Meythaler** et al. (US 6,682,508; hereafter Meythaler), or **Stone** (US 5,293,875), and in further view of **Goldberg** et al. (US 5,234,409; hereafter Goldberg).

The Kelly patent discloses a lumen having a proximate end and a distal end, an inflatable cuff surrounding the lumen, the lumen having first and second conduits, the first conduit in communication with the inflatable cuff, the second conduit in fluid communication with the proximate end of the lumen, a port at an end of the first conduit, and a one way valve in the port. The Kelly patent does not disclose the use of filters at the distal and proximal ends. However, such use would have been considered conventional in the art at the time the invention was made as evidenced by the teachings of Fisher, Thornton, Meythaler, or Stone.

The Fisher patent explicitly discloses hydrophobic filter tips. In column 3, lines 21-24, the specification states "the pair of gas inlets 38 are separated from central lumen 30 by a pair of hydrophobic gas permeable membranes 64". Similarly, the

Art Unit: 3763

Thornton patent also demonstrates the conventionality of designing catheters with hydrophobic tips. In relation to the use of filters in combination with infusion ports, Meythaler demonstrates that such use is well known in the art. Finally, Stone demonstrates that the use of hydrophobic and charcoal filters is also well known in the art.

In relation to the amended language in claims 1 and 7, the Goldberg patent demonstrates the conventionality of severing the proximal section of a catheter shaft in order to deflate the cuff and remove the catheter from the body. In column 5, starting in line 29, the specification explicitly states that “[t]o remove the device 10, the end of the conduit 12 is cut with a scissor upstream of the inflation valve 32 in order to bleed the inflation lumen 30 and deflate the bladder balloon 28. The conduit 12 may then be withdrawn from the urethra 22 and discarded”.

Based on the above observations, for a person of ordinary skill in the art, the modification of the Kelly catheter with:

(1) hydrophobic or charcoal filters positioned at the proximal or distal ends of said catheter, as taught by Fisher, Thornton, Meythaler, or Stone, and

(2) the use of a “one-way” valve to completely control the solution injected into the first conduit and allow inflation of the cuff but not allow deflation, forcing the cutting of the catheter to deflate the cuff, as taught by Goldberg, would have been considered obvious in view of the conventionality of these enhancements, and moreover, because by designing the catheter with a one-way valve, medical personnel is forced to destroy

Art Unit: 3763

the catheter in order to remove the catheter from the body, ensuring that the catheter is only used for one procedure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manuel A. Mendez whose telephone number is 571-272-4962. The examiner can normally be reached on 0730-1800 hrs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Nicholas D. Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Application/Control Number: 10/720,213
Art Unit: 3763

Page 5

/Manuel A. Mendez/

Primary Examiner, Art Unit 3763

Manuel A. Mendez
Primary Examiner
Art Unit 3763

MM